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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,491

09/05/2003

Dagmar Beyerlein

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11/23/2009

ABBOTT CARDIOVASCULAR SYSTEMS INC./BSTZ  
BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP  
1279 OAKMEAD PARKWAY  
SUNNYVALE, CA 94085-4040

EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/656,491	<b>Applicant(s)</b> BEYERLEIN, DAGMAR	
	<b>Examiner</b> CATHERINE N. WITCZAK	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-12 and 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/7/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

The indicated allowability of claim 25 is withdrawn in view of the newly discovered reference(s) to Kubota. Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-3, 6, 8, 11, 12 and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Gambale et al (US 6,248,112).

Gambale et al disclose in Figures 3F, 9A-C and column 7, line 44 - column 8, line 5 a device comprising a fluid source (110) and a needle (22) with first and second openings which open to the same lumen of the needle and are located apart at a predetermined distance, and a pressure sensor connected to the needle configured to measure no significant change in pressure as compared to a first pressure, a second pressure that is a significant increase in pressure as compared to the first pressure when the needle contacts tissue and the first opening becomes occluded, and a third pressure that is a significant increase in pressure as compared to the second pressure when the needle penetrates the tissues and the second opening becomes occluded; wherein readings from the detector are sent to a pressure detector (31) and displayed on an electronic readout.

### ***Claim Rejections - 35 USC § 103***

Art Unit: 3767

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 5, 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al.

Gambale et al discloses the claimed invention except for expressly disclosing the size of the aperture, distance of the aperture from the end of the needle, and outer/inner diameter of the syringe. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the are, distance, and diameters because Applicant has not disclosed that these values provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have been able to change these values in order to control the amount of flow and location of outflow as desired. Therefore, it would have been an obvious matter of design choice to modify Gambale et al to obtain the invention as specified in claims 5, 7, 9, and 10.

3. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al as modified by Kubota (US 4,299,230).

Gambale et al discloses the claimed invention except for disclosing the device comprising a visual or audio feedback system that indicates to an operator when to stop advancement of the needle because the penetration depth desired has been achieved as determined by using pressure readings. Kubota teaches in column 1, lines 20-40 and column 4, lines 24-49 that it is known to use a visual feedback system to indicate to an operator to stop advancement of a needle by gauging a feedback system dependant on the penetration depth of a needle. It would have been obvious to one having ordinary skill

Art Unit: 3767

in the art at the time the invention was made to modify the device of Gambale et al with the teachings of Kubota since such a modification would provide for a clear indication to an operator of the penetration of the device so as to ensure positioning the needle in the correct location so as to prevent any damage resulting from penetrating too far into the tissue.

### ***Response to Arguments***

Applicant's arguments filed 8/7/2009 have been fully considered but they are not persuasive. Applicant argues that Gambale does not disclose the claimed invention because the reference does not disclose a needle with a first opening to a lumen of the needle and a second opening to the same lumen of the needle. Examiner disagrees. Even though the multiple ports of Gambale's device have individual lumens which connect them to the pressure assembly, these individual lumens all extend through a common needle lumen, and thus Gambale teaches a needle having first and second opening to the same lumen of the needle in that the first opening is connected to a first lumen which lies in the main lumen of the needle and the second opening is connected to a second lumen which also lies in the same main lumen of the needle. Since Applicant has not claimed that the first and second openings have to have openings to the same lumen of a needle such that they are in fluid communication, it is the Examiner's position that the Gambale et al reference does teach a needle having first and second openings to the same lumen of the needle.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 8/7/2009 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3767

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witzak/

Application/Control Number: 10/656,491

Page 6

Art Unit: 3767

Examiner, Art Unit 3767

/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767